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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,223	08/12/99	KALLMEYER	G P8341-9011

HM12/0515
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WASHINGTON DC 20005-5701

EXAMINER

NICKOL, G

ART UNIT	PAPER NUMBER
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1642

12

DATE MAILED: 05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/308,223	Applicant(s) KALLMEYER ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21, 23-32, 34-36 is/are rejected.
- 7) ☒ Claim(s) 22 and 33 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 20) <input type="checkbox"/> Other: |

Response to Amendment

The Amendment filed March 9, 2001 (Paper No. 11) in response to the Office Action of October 16, 2000 is acknowledged and has been entered. Claims 13-36 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Withdrawn

The rejection of Claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicant's arguments on pages 2-3 of Paper No. 11.

The rejection of Claim 36 under 35 U.S.C. 102(e) as being anticipated by Fukuda et al. (US Patent No. 5,908,826, 1992) is withdrawn in view of applicant's amendment there to.

Rejections Maintained

Claims 13- 21, 23-32, and 34-35 remain rejected and newly amended claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al (WO 89/11297) in view of

Friedman et al. (US Patent No. 5750142) and Arizono et al. (Arzneimittelforschung, Vol. 44, No. 7, 1994) for the reasons of record in Paper No. 9, pages 4-7.

Applicants argue (Paper No. 11, page 6) that the teachings of Friedman et al. would not have been combined with Phillips et al. at the time of the invention, and that the combination of the two references would not result in the present invention because Friedman discloses that the composition disclosed, may contain a suspending agent such as gelatin or pectin or polyethylene glycol.

This argument has been considered but is not found persuasive because the disclosure by Friedman that the composition "may" contain a suspending agent, such as gelatin or pectin or polyethylene glycols (i.e. preferred embodiments) does not negate the combination of the references. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Applicants further argue that the composition of Friedman et al. does not contain a carbohydrate, and that the reference dissuades their use. Thus, applicants argue, since the present invention and Phillips require the use of a carbohydrate, Friedman et al. would not have been combined with Phillip et al. This argument has been considered but is not found persuasive. The previous rejection was not concerned with the presence or absence of a carbohydrate, but rather do the teachings of Friedman et al. suggest to one of ordinary skill in the art at the time the invention was made that the composition of Phillips et al. could be optimized by adding at least one amino acid and a surfactant. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it

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is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As such, Friedman et al. clearly teaches the advantages of incorporating at least one amino acid and a surfactant in that the inclusion of amino acids provides superior performance with respect to the droplet size of the reconstituted product (Friedman et al., column 2, line 27) and the addition of surfactants can be used to enhance the formation of the emulsion (Friedman et al., column 5, line 12). Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 22 and 33 remain objected to for the reasons of record in Paper No. 9, page 7.

New Objections

Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper to object to the claims as being substantial duplicates. See MPEP § 706.03(k).

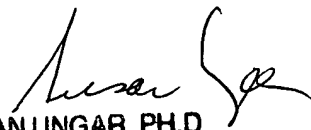
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

Gary B. Nickol, Ph.D.
Examiner
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May 11, 2001